

Food and Drug Administration, HHS

§ 1005.25

§ 1005.24 Costs of bringing product into compliance.

The costs of supervising the operations necessary to bring a product into compliance with the Act shall be paid by the owner or consignee who files an application pursuant to § 1005.21 and executes a bond under section 360(b) of the Act. Such costs shall include:

(a) Travel expenses of the supervising officer;

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law;

(c) *Service fees*: (1) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(2) The charge for the services of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-12/4 employee.

(3) The rate per hour equal to 266 percent of the equivalent hourly rate of regular pay of the supervising officer (GS-11/4) and the analyst (GS-12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hour weeks	2,080
Less:	
Nine legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	72
Annual Leave—26 days	208
Sick Leave—13 days	104
Total	384
Net number of working hours	1,696
Gross number of working hours in 52 40-hour weeks	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½% of annual rate of pay of employee	176
Equivalent annual working hours	2,256

	Hours
Support required to equal to 1 man-year	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation	4,512

NOTE: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours (4512/1696)=266 pct.

(d) The minimum charge for services of supervising officers shall be not less than the charge for 1 hour and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

[38 FR 28630, Oct. 15, 1973, as amended at 42 FR 55207, Oct. 14, 1977; 42 FR 62130, Dec. 9, 1977]

§ 1005.25 Service of process on manufacturers.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer's agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

(b) A manufacturer designating an agent must address the designation to the Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. It must be in writing and dated; all signatures must be in ink. The designation must be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation must disclose the manufacturer's full legal name and the name(s) under which the manufacturer conducts the business, if

applicable, the principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation must identify the marks, trade names, or other designations of origin which these products bear. The designation must provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent must be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

(c) Service of any process, notice, order, requirement, or decision specified in section 360(d) of the Radiation Control for Health and Safety Act of 1968 may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 360(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Center for Devices and Radiological Health and publishing a notice that such service was made in the FEDERAL REGISTER.

[38 FR 28630, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988; 65 FR 17137, Mar. 31, 2000]

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 351, 352, 360, 360e-360j, 371, 381; 42 U.S.C. 263b-263n.

SOURCE: 38 FR 28631, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

[40 FR 32257, July 31, 1975]

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.

(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Center for Devices and Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not